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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

JANSSEN PHARMACEUTICA N.V. and
JANSSEN PHARMACEUTICA PRODUCTS, L.P.,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, LTD. and
DR. REDDY'S LABORATORIES, INC.,

Defendants.

Civ. Action No. 03 CV 6185
(JWB)

Return Date: September 12, 2005

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JANSSEN PHARMACEUTICA N.V. and
JANSSEN PHARMACEUTICA PRODUCTS, L.P.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Civ. Action No. 03 CV 6220
(JWB)

**JANSSEN PHARMACEUTICA N.V. AND JANSSEN PHARMACEUTICA
PRODUCTS, L.P.'S OPPOSITION TO MYLAN'S APPEAL TO VACATE
THE JUNE 29, 2005 ORDER OF MAGISTRATE JUDGE HANEKE**

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Plaintiffs Janssen Pharmaceutica N.V. and Janssen Pharmaceutica Products, L.P. (collectively "Janssen") oppose Mylan Pharmaceuticals Inc.'s ("Mylan") appeal of Magistrate Judge Haneke's June 29, 2005 Order denying Mylan's motion to compel and granting Janssen's cross-motion for a protective order relating to Janssen's risperidone NDA and IND ("NDA/IND") and Janssen's pirenperone clinical testing documents.

PRELIMINARY STATEMENT

This is Mylan's second appeal of a discovery order issued by Judge Haneke in this case. Mylan's strategy throughout this litigation has been to harass Janssen by making unduly burdensome discovery demands. Even though Mylan requested and received a short discovery period at the beginning of this case, Mylan has dragged out discovery to over fourteen months, which included two separate extensions of the discovery date due to Mylan's refusal to produce documents and witnesses in a timely fashion. Mylan's latest appeal of Judge Haneke's discovery ruling is delaying this case further, nearly guaranteeing that this case will not be decided before the 30-month Hatch-Waxman statutory stay that is currently in place. Janssen will be seriously prejudiced by Mylan's continuous tactics of delaying this case from moving forward.

Even more troubling is that the discovery Mylan is seeking in its latest appeal of Judge Haneke's Order is completely unrelated to any claim and defense

actually in this case. Mylan insists that it needs to review Janssen's entire NDA/IND to support its alleged inequitable conduct defense. The problem is that Mylan has never pled an inequitable conduct defense in this case. After fourteen months of discovery that included over 80 document requests resulting in the production of over 220,000 pages of documents, 10 interrogatories, 48 Requests for Admissions, and over 10 different personal and 30(b)(6) witnesses for depositions, Mylan has not set forth any evidence that Janssen has ever committed inequitable conduct. Nevertheless, Mylan argues there "might" be a statement in the NDA/IND that can possibly be used as support for an inequitable conduct defense. Such speculation of might or possibility does not place a defense in a case. Thus, Judge Haneke properly denied Mylan's motion to compel and entered a protective order to prevent Mylan from embarking on a fishing expedition into Janssen's sensitive NDA/IND documents when Mylan's request for doing so was unrelated to any pled claim or defense.

STATEMENT OF FACTS

Mylan and Dr. Reddy's Laboratories ("DRL") filed separate Abbreviated New Drug Applications (ANDAs) with the FDA to market generic versions of Janssen's antipsychotic drug, known as Risperdal. Both Mylan and DRL filed Paragraph IV Notices certifying that the '663 patent is invalid and would

not be infringed by their proposed generic products. In response, Janssen sued Mylan and DRL separately for patent infringement.

Janssen's suit against Mylan was filed on December 29, 2003. See Mylan Ex. 11. Mylan answered Janssen's Complaint on February 4, 2004 and asserted that Mylan did not infringe the '663 patent and that the '663 patent is invalid due to obviousness. On July 30, 2004, Mylan filed an amended Answer removing the defense of non-infringement and maintaining the defense of invalidity due to obviousness. Mylan has never asserted the defense of inequitable conduct in either its Answer or amended Answer.

In the course of discovery in this case, Mylan has served 85 document requests to Janssen. In its First Set of Document Requests dated March 22, 2004, Mylan included the following two documents requests:

62. All documents and things relating to communications between Janssen and the FDA or any other regulatory Authority regarding Risperidone, Compound 11, Pirenperone or Ketanserin.

75. All documents relating to any NDA for any oral tablet containing Risperidone.

Mylan argues that these two requests encompass Janssen's risperidone NDA and IND and that Janssen agreed to produce these documents. It may be true that among many other documents, the requests may call for the production of the NDA and IND. But, it is not true that Janssen agreed to produced the NDA and

IND. Instead, within the 30 days provided by Federal Rule of Civil Procedure 34, Janssen objected to both of these requests as being "overly broad and unduly burdensome" and that the requests called for the "production of documents that are neither relevant nor reasonably calculated to lead to the discovery of admissible evidence." See Mylan Ex. 16.

Mylan never disputed Janssen's timely objections to requests 62 and 75. In fact, Mylan proceeded with discovery fully aware that Janssen objected to producing its NDA/IND. In particular, Mylan never brought up the issue of Janssen's NDA/IND in any of its allotted 10 depositions, 10 interrogatories, or 48 Requests for Admissions.

Notably, in one of Mylan's numerous 30(b)(6) deposition categories served on Janssen, Mylan requested Janssen to produce a 30(b)(6) deposition witness relating to Janssen's NDA/IND. The 30(b)(6) Category stated:

Janssen's filing with the United States Food & Drug Administration of any New Drug Application, Abbreviated New Drug Application, Drug Master File or Investigational New Drug Application with respect to Identified Piperidinyl Compounds.

Attached hereto as Exhibit A, at 6.

Janssen objected to this 30(b)(6) Category in a letter dated November 5, 2004. Specifically, Janssen stated:

Janssen objects to this Category in that it is seeking testimony that is irrelevant to the issues in this case. The

FDA filings related to any of these compounds is irrelevant to this case. Thus, Janssen will not produce a witness on this Category.

Attached hereto as Exhibit B, at 5.

Once again, Mylan did not dispute Janssen's objection to producing a 30(b)(6) witness relating to Janssen's NDA/IND and did not seek Judge Haneke's intervention after Janssen's objection.

This is in contrast to how Mylan conducted discovery as to many other issues in this case where Mylan regularly took issue with Janssen's refusal to produce documents and witnesses and regularly sent letters to Judge Haneke requesting his intervention on many of these issues.¹ Mylan even unsuccessfully appealed one of these issues decided by Judge Haneke to this Court. Thus, Mylan was aggressive during discovery to promptly seek the Court's intervention to any documents Mylan believed it was entitled to that Janssen had not produced. Even though Mylan admits that it initially requested the NDA/IND on March 22, 2004, Mylan did not request Judge Haneke's intervention on this issue until March 16, 2005, nearly a year after Janssen objected to the discovery and after the original discovery cutoff date of November 15, 2004, and original extended discovery cutoff date of March 15, 2005.² Mylan's actions demonstrate that it did not

¹ Judge Haneke sustained all of Janssen's objections to Mylan's burdensome requests for irrelevant documents and witnesses.

² Mylan does not explain why it did not seek these documents before the original discovery cutoff of November 15, 2004, or the first extended discovery cut-off date of March 15, 2005. Fact discovery was extended twice due to Mylan and DRL's failure to produce documents and witnesses. It is

originally dispute Janssen's objections to producing its NDA/IND. Clearly, if Mylan had really disputed Janssen's objection to producing the NDA/IND or a 30(b)(6) witness on these topics, it should have brought this issue to the Court's attention earlier during discovery, just as it did on many other issues.

Even though Mylan re-issued its request for Janssen's NDA/IND eleven months later and near the end of the extended discovery deadline, Janssen was still willing to produce portions of the NDA or IND that were relevant to Mylan's pled defenses. However, the entire NDA and IND encompassed approximately 120 boxes of material and producing this amount of documents will pose a significant burden on Janssen this late in discovery. See Mylan Ex. 3. For this reason, Janssen requested that Mylan narrow its request to documents in the NDA and IND that Mylan believed were relevant to issues actually in the case. Instead, Mylan demanded the entire NDA and IND.

When Janssen objected to producing the entire NDA/IND, Mylan moved to compel its production. Mylan's arguments to Judge Haneke focused on its potential inequitable conduct defense, a defense that it has not pled. Because the NDA/IND is enormous in volume and contains confidential Janssen trade secrets, Judge Haneke denied Mylan's motion because discovery had gone on too long in this case and Mylan never pled an inequitable conduct defense.

inequitable for Mylan to use those extensions caused by its own delay to its advantage by seeking additional documents that it could have sought before the original deadline, but chose not to.

Finally, in response to numerous Mylan document requests regarding pirenperone, Janssen produced every document it was able to locate regarding pirenperone. When Mylan objected and wanted certain other documents relating to pirenperone, Janssen searched to determine whether any of these pirenperone documents existed. After a thorough search, Janssen was not able to locate any other documents related to pirenperone whether it was tested as an antipsychotic or anti-anxiety medication. Thus, there are no other pirenperone documents that Janssen is aware of despite Mylan's objections otherwise, and Mylan's motion and appeal are frivolous.

ARGUMENT

I. BECAUSE MYLAN'S MOTION PERTAINS TO A DISCOVERY DISPUTE, THIS COURT SHOULD REVIEW JUDGE HANEKE'S ORDER USING A CLEARLY ERRONEOUS STANDARD

Mylan argues that this Court's review of Magistrate Haneke's Order should be *de novo* because Judge Haneke essentially struck Mylan's defense of inequitable conduct by not allowing Mylan to review Janssen's NDA/IND. Mylan's arguments are baseless. Mylan never pleaded this defense. Thus, there is no defense to be stricken. Moreover, the mere denial of some discovery is not a dispositive issue: otherwise, every discovery motion would be "dispositive." This is especially true in the case where Janssen has produced documents and witnesses (such as the inventor and prosecuting attorneys) which could have been used to

develop an inequitable conduct case. Of course, since no inequitable conduct was committed, Mylan has been unable to develop one and must resort to mere speculation. The denial of some discovery on an issue where a party has taken substantial discovery is not the equivalent of an order to strike.

Mylan's motion here pertains to a discovery dispute - which is a non-dispositive issue. As such, the proper standard for this Court to apply here is an abuse of discretion standard that is extremely deferential to the Magistrate Judge's discretion. Mosaid Techs. Inc. v. Samsung Elecs. Co., 2004 WL 2550309, at *2 (D.N.J. Oct. 1, 2004), aff'd in part, 348 F. Supp. 332 (D.N.J. 2004) (court rejecting *de novo* review of magistrate's order and recognized that even if the order had the potential to affect the outcome of an issue, the order should still be reviewed under the deferential standard). A district court may not reverse a Magistrate Judge's determination of a non-dispositive issue unless it is clearly erroneous or contrary to law. 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); Local Civ. R. 72.1(c)(1)(A). Where a Magistrate Judge has ruled on a non-dispositive matter such as a discovery motion, his or her ruling is entitled to great deference and is reversible only for abuse of discretion. Kresefky v. Panasonic Communications & Sys. Co., 169 F.R.D. 54, 64 (D.N.J. 1996). This deferential standard of review is "especially appropriate where the Magistrate Judge has managed this case from the outset and developed a thorough knowledge of the proceedings." Public Interest Research

Group v. Hercules, Inc., 830 F. Supp. 1525, 1547 (D.N.J. 1993), aff'd on other grounds and rev'd on other grounds, 50 F.3d 1239 (3d Cir. 1995). Thus, because Judge Haneke's order relates to a discovery dispute, this Court reviews that ruling on an a clearly erroneous standard.

II. THIS COURT SHOULD REJECT MYLAN'S REQUEST FOR JANSEN'S NDA/IND BECAUSE MYLAN HAS NO EVIDENCE THAT JANSSEN COMMITTED INEQUITABLE CONDUCT

Mylan's central argument is that it must have access to Janssen's NDA/IND in order to possibly plead an inequitable conduct defense. But this is nothing more than a fishing expedition seeking discovery on an issue that is not part of this case. Such a fishing expedition to possibly develop facts to support an unpled defense is contrary to the Federal Rules of Civil Procedure. Federal Rule 26(b)(1) limits discovery to "any matter, not privileged, that is relevant to the claim or defense of any party" As the 2000 Advisory Notes to the rule make clear, a party has no right to seek discovery on an unpled defense:

The rule change signals to the court that it has the authority to confine discovery to the claims and defenses asserted in the pleadings, and signals to the parties that they have no entitlement to discovery to develop new claims or defenses that are not already identified in the pleadings.

Mylan has never pled the defense of inequitable conduct and thus it is well within the discretion of Judge Haneke to deny Mylan access to Janssen's NDA/IND.³

This limitation on discovery is especially true for inequitable conduct. The Federal Circuit frowns upon vague allegations of inequitable conduct and has expressed concern over the use of the inequitable conduct defense as a "magic incantation to be asserted against every patentee." FMC Corp. v. Manitowoc Co., Inc., 835 F.2d 1411, 1415 (Fed. Cir. 1987). Specifically, the Federal Circuit has stated:

The habit of charging inequitable conduct in almost every major patent case has become an absolute plague. Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds, to represent their clients interest adequately perhaps. . . . They destroy the respect for one another's integrity, for being fellow members of an honorable profession, that used to make the bar a valuable help to the courts in making a sound disposition of their cases, and to sustain the good name of the bar itself. A patent litigant should be made to feel, therefore, that an unsupported charge of "inequitable conduct in the Patent Office" is a negative contribution to the rightful administration of justice.

Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988)
(emphasis added).

³ Mylan's argument that it was faced with a "paradox" because it does not know what sections of the NDA/IND to ask for is nothing but a red herring. Mylan has argued that the materials are relevant to its unpled – and untrue – inequitable conduct defense. However, because Mylan never pled the defense of inequitable conduct, any requests for sections of the NDA/IND related to an inequitable conduct defense are not appropriate.

Thus, to assert an inequitable conduct defense, Federal Rule 9(b) requires that a defendant must plead the defense with particularity. E.g., Ferguson Beauregard/Logic Controls v. Mega Sys., LLC, 350 F.3d 1327, 1344 (Fed. Cir. 2003); Sun-Flex Co. v. Softview Computer Prod. Corp., 750 F. Supp. 962, 963 (N.D. Ill. 1990); Intel Corp. v. Hyundai Elecs. Am., Inc., 692 F. Supp. 1113, 1115-16 (N.D. Cal. 1987). This is an important limitation. Without it, a defendant may use an inequitable conduct charge to embark on a fishing expedition into patentee's documents. As one court recognized, "[v]ague allegations of inequitable conduct may also be the launching of a 'fishing expedition' allowing the accuser to embark on wide-ranging discovery upon a thimble full of facts." Chiron Corp. v. Abbott Labs., 156 F.R.D. 219, 221 (N.D. Cal. 1994).

Here, Mylan's argument falls squarely within the Federal Circuit's warning that the use of the inequitable conduct defense should be disfavored. Mylan has no theory of inequitable conduct – let alone a sufficient basis to plead it. Despite that infirmity, it is improperly seeking wide ranging discovery of highly sensitive information. This is precisely the sort of tactical maneuvering that Rule 9(b) is designed to deter. Id. (citing Semegen v. Weidner, 780 F.2d 727, 731 (9th Cir 1985)).

Mylan's reliance on cases such as Merck & Co. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1421 (Fed. Cir. 1989), and Bruno Indep. Living

Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1351-52 (Fed. Cir. 2005) are also misplaced. Unlike the facts in Merck and Bruno, Mylan has never alleged that Janssen had withheld significant prior art from the Patent Office. Instead, the art that Mylan contends is the closest prior art, U.S. Patent No. 4,342,870, which discloses pirenperone, was considered by the Examiner of the patent in suit. Thus, Mylan is not entitled to burden Janssen on the eve of the extended discovery deadline with new discovery that Mylan cannot relate to any of its pleaded defenses.

III. JUDGE HANEKE PROPERLY DENIED MYLAN'S MOTION TO COMPEL AND FOUND GOOD CAUSE TO ISSUE A PROTECTIVE ORDER RELATING TO JANSSEN'S RISPERIDONE NDA/IND

Mylan attempts to frame Judge Haneke's Order as one that only grants Janssen a protective order regarding its NDA/IND. However, Mylan ignores the fact that Judge Haneke's order also denied Mylan's motion to compel Janssen's NDA/IND. Specifically, Judge Haneke's order states:

ORDERED that:

1 Mylan's motion to compel production of the documents and testimony first addressed in its March 16, 2005 letter and again in its March 30, 2005 letter is denied; and Janssen's responsive motion for a protective order included in its April 29, 2005 letter is granted.

See Mylan Ex. 1.

In its brief, Mylan does not address why Judge Haneke erred in denying Mylan's motion to compel. Rather, Mylan focused solely on Judge Haneke's granting of a protective order. This alone is reason to deny Mylan's appeal of Judge Haneke's order.

Nevertheless, Judge Haneke properly denied Mylan's motion to compel. Although the scope of discovery under Rule 26(b)(1) is broad, it is not unlimited. Kopacz v. Delaware River & Bay Auth., 225 F.R.D. 494, 497 (D.N.J. 2004). A motion to compel is addressed to the discretion of the district court. Lesal Interiors, Inc. v. Resolution Trust Corp., 153 F.R.D. 552, 558 n. 4 (D.N.J. 1994). The requesting party of a motion to compel bears the burden of demonstrating that the requested documentation is relevant to a pled issue – not merely possibly relevant to an unpled defense – and not overly burdensome. Fed. R. Civ. P. 26(b)(1) and 26(b)(2). Here, Judge Haneke determined that Mylan's request for the NDA/IND was not relevant because it was not being requested for any pleaded defense. In addition, because Mylan requested the NDA/IND so late in the extended discovery period, it would have been unduly burdensome for Janssen to produce the NDA/IND in such a short period of time. Thus, Judge Haneke properly denied Mylan's motion to compel.

In addition to denying Mylan's motion to compel, Judge Haneke properly granted Janssen's cross-motion for a protective order. Federal Rule 26(c)

gives broad discretion to the district court to issue a variety of orders for the protection of the parties and witnesses in the discovery process. Rodgers v. U.S. Steel Corp., 536 F.2d 1001, 1006 n.12 (3d Cir. 1976). Specifically Federal Rule 26(c) states:

Upon motion by a party or by the person from whom discovery is sought . . . and for good cause shown, the court in which the action is pending . . . may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including . . . that . . . discovery not be had.

(emphasis added).

Mylan argues that Janssen did not show good cause for Judge Haneke to enter a protective order. However, a judge must be allowed broad discretion in guiding the discovery process to effectively manage complex litigation. See Marrese v. Am. Acad. of Orthopaedic Surgeons, 726 F.2d 1150, 1158-59 (7th Cir 1984), rev'd on other grounds, 470 U.S. 373 (1985). In fact, a court may enter a protective order sua sponte. Lesal Interiors, 153 F.R.D. at 558 n. 4. Even if the requested evidence is marginally relevant – which it is not – it is still subject to the limitation of Rule 26(c) if the discovery would cause an undue burden or expense. Ferguson v. Lion Holding, Inc., 2005 WL 1216300, at *3 (S.D.N.Y. May 23, 2005). Similarly, Rule 26(b)(2) provides limits on discovery if, among other things, "the party seeking discovery has had ample opportunity by discovery in the

action to obtain the information sought" or "the burden or expense of the proposed discovery outweighs its likely benefit."

In the present case, in order to move this case along, Judge Haneke used his discretion to deny Mylan access to Janssen's NDA/IND. He did so because Mylan waited for over a year before specifically seeking the NDA/IND; discovery had progressed for over fifteen months and the case currently has already progressed into the expert discovery phase (although it has been stayed until this appeal is decided); and Mylan's basis for requesting the NDA/IND is to determine whether it can possibly plead an inequitable conduct defense. Judge Haneke determined that at this stage of the case, Mylan's need for the NDA/IND was outweighed by the burden it would have imposed on Janssen and the progression of the litigation.

Furthermore, Janssen's NDA/IND contains highly competitive trade secret information. These documents contain manufacturing data and other data that have absolutely no relevance to this action, but would be highly valuable to a competitor. Courts presume that disclosure of technical confidential company information, such as information contained in the NDA/IND, to be harmful if produced to a competitor and therefore, Mylan must show a "substantial need" for the discovery. Echostar Communications Corp. v. News Corp. Ltd., 180 F.R.D. 391, 394 (D. Colo. 1998). Even with the current protective order in place, Mylan's

use of any of the NDA/IND at trial will make it public.⁴ Such a public dissemination of Janssen's confidential business information would be highly damaging to Janssen, especially when balanced against Mylan's reasons for requesting the information. United States v. United Fruit Co., 410 F.2d 553, 556 (5th Cir. 1969) (citing 4 Moore's Federal Practice, 2d Ed., 1964) ("There is no true privilege against discovery of trade secrets or other 'confidential' business information, but the courts nevertheless will exercise their discretion to avoid unnecessary disclosure of such information particularly where the action is between competitors.").

IV. THE NDA IS IRRELEVANT

Mylan claims that Janssen has admitted the relevance of the NDA/IND because Janssen relied on the NDA/IND to receive a patent extension to the '663 patent. See Mylan Brief at 3. Mylan's characterization of Janssen's actions is misleading. Patent extensions are granted if the FDA delays in approving Janssen's NDA. There are no substantive considerations in evaluating this extension.

Furthermore, this case is about the infringement and validity of Janssen's '663 patent – not about Janssen's NDA/IND on risperidone. Thus, Janssen's NDA/IND is not relevant to any issue in this case. Further, even if the

⁴ This is not some speculative harm – it has occurred several times to various Johnson & Johnson companies.

NDA/IND were relevant, that does not mean that there are no limits to discovery.

"Practical considerations dictate that parties should not be permitted to roam in shadow zones of relevancy and to explore matter which does not presently appear germane on the theory that it might conceivably become so." McCurdy v. Wedgewood Capital Mgmt. Co., 1998 WL 964185, at *9 (E.D. Pa. Nov. 16, 1998).

Mylan's threadbare suggestion that perhaps Janssen committed inequitable conduct and that there might be some evidence in the NDA/IND is insufficient to justify this voluminous and overburdensome discovery so late in the case. Such speculation is not enough.

Mylan's citation to Conopco, Inc. v. Warner-Lambert Co., 1999 WL 1565082 (D.N.J. Jan. 24, 2000), does not help Mylan. In Conopco, the patentee was inspecting defendant's documents relating to the alleged infringing product in order to prove its infringement case. The Court ordered that the patentee provide all the documents related to the product rather than having the patentee request certain documents. This is in contrast to the present case where Mylan is not requesting to view Janssen's NDA/IND to determine infringement or any defense that it has pled in this case.

V. MYLAN HAS ALL OF JANSSEN'S PIRENPERONE DOCUMENTS

In addition to the NDA/IND documents, Mylan also continues to seek documents on pirenperone – a product not covered by the claims of the '663 patent.

However, Mylan has the very documents it seeks. Janssen stated to Mylan on numerous occasions that Janssen has provided to Mylan all documents in its possession related to pirenperone, regardless of whether the documents were related to pirenperone as an anti-anxiety or antipsychotic medication. Janssen has searched its medical document system database for all documents related to pirenperone and has produced them to Mylan. Janssen is not in possession of any other documents related to pirenperone.

VI. JANSSEN'S MOTION FOR A PROTECTIVE ORDER WAS TIMELY

Mylan argues that Janssen's protective order was untimely. This argument lacks any merit. This argument continues Mylan's misleading argument that Judge Haneke merely entered a protective order. What it fails to consider is that not only did Judge Haneke enter a protective order, but he also denied Mylan's motion to compel. Even if this waiver argument was valid – which it is not – it would have no bearing on Judge Haneke's denial of Mylan's motion to compel. Even if the protective order was vacated, Janssen would not be compelled to produce the documents.

Regardless, Janssen's actions were all timely. Mylan served its initial document requests on March 22, 2004. As per Federal Rule 34, Janssen timely objected to Mylan's document requests including requests Nos. 62 and 75, thirty days later on April 21, 2004. See Mylan Ex. 16. As Rule 34 explicitly states, that

is all that a party needs to do to preserve its objections. Specifically, Rule 34 states:

The party upon whom the request is served shall serve a written response within 30 days after the service of the request. . . . The response shall state, with respect to each item or category, that inspection and related activities will be permitted as requested, unless the request is objected to, in which event the reasons for the objection shall be stated. . . . The party submitting the request may move for an order under Rule 37(a) with respect to any objection to or other failure to respond to the request or any part thereof, or any failure to permit inspection as requested.

(emphasis added). Instead of putting the burden of seeking judicial intervention on Janssen, the objecting party, Rule 34 puts the burden of seeking judicial intervention on Mylan, the requestor. Neither Rule 34 nor Rule 26 make any limitations on when a party can seek a protective order.

Despite Rule 34 placing the burden on Mylan to move to compel and not Janssen to seek a protective order, Mylan waited a year before moving for an order regarding Janssen's objections to Mylan requests Nos. 62 and 75. When Mylan did file its motion to Judge Haneke, Janssen timely responded and cross-moved for a protective order. Thus, there was nothing untimely regarding Janssen's request for a protective order. If any party was untimely, it was Mylan.

None of Mylan's cases are even remotely on point. For example, in United States v. IBM Corp., 79 F.R.D. 412 (S.D.N.Y. 1978), the movant first

sought a protective order on reargument, after the Court had ordered the documents produced. Similarly irrelevant are Nestle Foods Corp. v. Aetna Cas. & Sur. Co., 129 F.R.D. 483 (D.N.J. 1990) and United States v. Panhandle E. Corp., 118 F.R.D. 346, 351 (D. Del. 1988), where the issue involved whether a protective order to treat documents that had been produced or agreed to be produced should be treated as confidential. Finally, in Gurnicz v. Guindon, 1991 WL 21606 (E.D. Pa. Feb. 15, 1991), the movant did not object to the document requests within the 30 days provided by Rule 34.

This case does not seek a protective order requesting that documents that have been produced or were agreed to be produced should be kept confidential. Nor does it involve a protective order regarding documents that the Court has ordered to be produced. Nor does it involve a party who failed to object to a document request within the 30 days provided by Rule 34. Instead, it involves a party who timely objected to the request for irrelevant documents according to Rule 34. Janssen's actions were timely and in accord with Rule 34. If anything, Mylan's year long delay, waiting until after both the original discovery cutoff date and the first extended discovery cutoff date, before bringing to issue to the Court was untimely.

CONCLUSION

For the foregoing reasons, Janssen requests that this Court deny Mylan's Motion to Vacate the June 29, 2005 Order of Magistrate Judge Haneke.

Respectfully submitted by:

/s/ Douglas S. Eakeley
Douglas S. Eakeley
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65 Livingston Avenue
Roseland, New Jersey 07068
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New York, New York 10036-6710
(212) 336-2000

*Attorneys for Plaintiffs Janssen Pharmaceutica N.V. and
Janssen Pharmaceutica Products, L.P.*

Dated: August 29, 2005

EXHIBIT A

Arnold B. Calmann (AC-3245)
Jeffrey Soos (JS-0589)
**SAIBER, SCHLESINGER, SATZ &
GOLDSTEIN, LLC.**
One Gateway Center – 13th Floor
Newark, NJ 07102-5311
(973) 622-3333

Attorneys for Defendant
Mylan Pharmaceuticals, Inc.

Robert F. Green
John E. Rosenquist
Christopher T. Griffith
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, 49th Floor
Chicago, IL 60601-6780
(312) 616-5600

**UNITED STATES DISTRICT COURT FOR THE DISTRICT
FOR THE DISTRICT OF NEW JERSEY**

JANSSEN PHARMACEUTICA N.V., and
JANSSEN PHARMACEUTICA
PRODUCTS, L.P.,

Plaintiffs and Counterclaim
Defendants,

v.

MYLAN PHARMACEUTICALS, INC.,

Defendant and Counterclaim
Plaintiff.

Civil Action No. 2:03-CV-06220

Judge John W. Bissell

Magistrate Judge
G. Donald Haneke

JANSSEN PHARMACEUTICA N.V., and
JANSSEN PHARMACEUTICA
PRODUCTS, L.P.,

Plaintiffs and Counterclaim
Defendants,

v.

DR. REDDY'S LABORATORIES, LTD. and
DR. REDDY'S LABORATORIES, INC.,

Defendants and
Counterclaim Plaintiffs.

Civil Action No. 2:03-CV-06185

Judge John W. Bissell

Magistrate Judge
G. Donald Haneke

**MYLAN PHARMACEUTICALS, INC.'S
NOTICE OF VIDEOTAPE DEPOSITION OF
PLAINTIFFS PURSUANT TO FED. R. CIV. P. 30(b)(6)**

To: Douglas S. Eakeley, Esq.
Lowenstein Sandler, P.C.
65 Livingston Avenue
Roseland, NY 07068

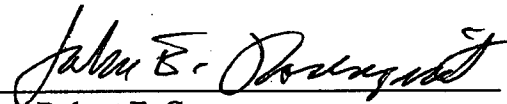
Scott B. Howard, Esq.
Patterson, Belknap, Webb & Tyler, LLP
1133 Avenue of the Americas
New York, NY 10036

PLEASE TAKE NOTICE that Defendant Mylan Pharmaceuticals, Inc. ("Mylan") will take the videotaped deposition upon oral examination of Plaintiffs Janssen Pharmaceutica N.V. and Janssen Pharmaceutica Products, L.P. (collectively "Janssen") on November 11, 2004, commencing at 9:30 a.m., and continuing thereafter until completed, at the offices of Saiber, Schlesinger, Satz and Goldstein, LLC, One Gateway Center, 13th Floor, Newark, NJ 07102, before a Notary Public or other officer fully authorized to administer oaths. The examination will be recorded by videographic and/or stenographic means. You are invited to attend and cross-examine.

Pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, Janssen is required to designate one or more appropriate persons to testify on its behalf with respect to each of the categories set forth in the attached Exhibit A, and the person(s) so designated shall be required to testify as to each of those categories known or reasonably available to Janssen.

Respectfully submitted,

Dated: October 26, 2004

By: 
Robert F. Green
John E. Rosenquist
Christopher T. Griffith
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, 49th Floor
Chicago, IL 60601-6780
(312) 616-5600

and

Arnold B. Calmann (AC-3245)
Jeffrey Soos (JS-0589)
**SAIBER, SCHLESINGER, SATZ &
GOLDSTEIN, LLC.**
One Gateway Center – 13th Floor
Newark, NJ 07102-5311
(973) 622-3333

EXHIBIT A

Janssen is hereby requested to designate one or more officers, directors, managing agents or other persons who consent to testify on its behalf who have knowledge on the topics hereinafter set forth.

INSTRUCTIONS AND DEFINITIONS

1. "Janssen" or "Plaintiffs" means Janssen Pharmaceutica N.V., Janssen Pharmaceutica Products, L.P., their past or present officers, directors, employees, shareholders, representatives, agents, attorneys and outside consultants, as well as any past or present predecessors, successors, parents, subsidiaries, or affiliates thereof, whether domestic or foreign, whether owned in whole or in part.
2. "Ketanserin" means 3-[2-[4-(4-fluorobenzoyl)-1-piperidinyl]ethyl]-2,4(1H,3H)-quinazolinedione and its metabolites.
3. "Pirenperone" means 3-[2-[4-(4-fluorobenzoyl)-1-piperidinyl]ethyl]-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one and its metabolites.
4. "Compound 10" and "compound 11" mean 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one and its metabolites.
5. "Risperidone" means 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one and its metabolites.
6. "Identified Piperidinyl Compounds" means any one or more of ketanserin, pirenperone, compound 10, compound 11 or risperidone.

7. "Testing" means subjecting the specified subject matter to any measurement, observation, analysis or methodology.

8. "Pharmacological" is defined in accordance with Ludo E. Kennis' use of that phrase during his deposition on October 20, 2004, and includes but is not limited to, *in vivo*, *in vitro* and cardiovascular testing.

CATEGORIES

1. Pharmacological, animal, pre-clinical, clinical, receptor-binding and other testing of ketanserin from the date of its first synthesis by Janssen through and until approximately April of 1985.

2. Pharmacological, animal, pre-clinical, clinical, receptor-binding and other testing of pirenperone from the date of its first synthesis by Janssen through and until approximately April of 1985.

3. Pharmacological, animal, pre-clinical, clinical, receptor-binding and other testing of compound 10 and compound 11 from their respective dates of first synthesis by Janssen through and until approximately January of 1994.

4. Pharmacological, animal, pre-clinical, clinical, receptor-binding and other testing of risperidone from the date of its first synthesis by Janssen through and until approximately January of 1994.

5. The pharmacological, animal, pre-clinical, clinical, receptor-binding and other testing of any salts, hydrates, polymorphs, active moieties and physical states thereof (including intermediates), as well as all dosage forms such as oral or injectable formulations, of ketanserin,

pirenperone, compound 10, compound 11 and risperidone from the date Janssen first synthesized each such compound through and until approximately January of 1994.

6. Janssen's filing with the United States Food & Drug Administration of any New Drug Application, Abbreviated New Drug Application, Drug Master File or Investigational New Drug Application with respect to the Identified Piperidinyl Compounds.

CERTIFICATE OF SERVICE

I hereby certify that on this 26th day of October, 2004, **MYLAN PHARMACEUTICAL, INC.'S NOTICE OF DEPOSITION OF PLAINTIFFS PURSUANT TO FED. R. CIV. P.**

30(b)(6) was served via facsimile and Federal Express, upon the following counsel of record:

Douglas S. Eakeley, Esq.
Lowenstein Sandler, P.C.
65 Livingston Avenue
Roseland, NJ 07068

Scott B. Howard, Esq.
Patterson, Belknap, Webb & Tyler, LLP
1133 Avenue of the Americas
New York, NY 10036-6710

Alan H. Pollack, Esq.
Budd Lerner, P.C.
150 John F. Kennedy Parkway
Short Hills, NJ 07078-0999

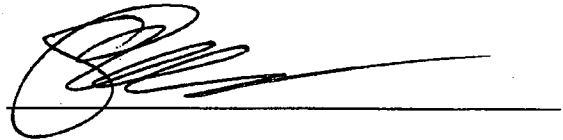
A handwritten signature in black ink, appearing to be "Alan H. Pollack", is written over a horizontal line.

EXHIBIT B

Patterson, Belknap, Webb & Tyler LLP

1133 Avenue of the Americas
New York, NY 10036-6710
(212) 336-2000
Fax (212) 336-2222

Scott M. Brown

Direct Phone
(212) 336-2124

Email Address
smbrown@pbwt.com

November 5, 2004

By Fax and Fedex

John Rosenquist
Leydig, Voit & Mayer
Two Prudential Plaza
180 North Stetson Avenue
Suite 4900
Chicago, IL 60601-6780

Re: Janssen v. Mylan
Janssen v. DRL

Dear John:

This letter is Janssen's response to Mylan's three Notices of 30(b)(6) Deposition Testimony served on Janssen on October 26th and October 28th. Mylan served two separate 30(b)(6) Notices on October 26th. The first Notice has five Categories ("Notice 1") and the second Notice has six Categories ("Notice 2"). Mylan's third Notice was served on October 28th and has seven Categories ("Notice 3").

As an initial matter, Janssen objects to Mylan's abusive practice of noticing countless number of 30(b)(6) Categories on Janssen. To date, we have estimated that Mylan has noticed at least seventy 30(b)(6) Categories including subcategories of Janssen testimony. Mylan's continuous practice of serving such a large number of 30(b)(6) categories on Janssen is unduly burdensome and oppressive. This is a clear violation of both the letter and the spirit of the limitation of depositions in this case. Nonetheless, and without waiving the objection, Janssen will respond as appropriate.

Furthermore, due to the number of 30(b)(6) Categories Mylan has recently noticed at this late stage of discovery, Janssen will be unable to go forward with any deposition before the November 15, 2004 discovery deadline. We will try to schedule any deposition as soon as possible. Notwithstanding the above, Janssen responds to Mylan's Notices as follows:

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Notice 1

1. General methods and practices employed by Janssen's Prior Art Studies (department) from about 1974 through and including about 1985.

Janssen objects to this Category due to Mylan's inaccurate definition of "prior art." As was clearly stated at the Kennis and Merten depositions, the "prior art department" at Janssen had nothing to do with searching for prior art as it pertains to 35 U.S.C. §§ 102 and/or 103. Rather, the department performed literature searches to help perform the synthesis of various compounds. Thus, the prior art department was not connected to the patent department. In addition, Janssen objects to this Category because Mylan already had a full opportunity to question Mr. Kennis and Mr. Mertens on this topic and thus any testimony on the topic will likely be duplicative. Subject to these objections, Janssen will provide you with the name of a witness shortly.

2. Any studies or other investigations conducted by, or for the benefit of, Janssen's Prior Art Studies (department) from about 1974 through and including about 1985 regarding prior art or potential prior art to the Identified Piperidinyl Compounds.

Janssen objects to this Category due to Mylan's inaccurate definition of "prior art." As was clearly stated at the Kennis and Merten depositions, the "prior art department" at Janssen had nothing to do with searching for prior art as it pertains to 35 U.S.C. §§ 102 and/or 103. Rather, the department performed literature searches to help perform the synthesis of various compounds. Thus, the prior art department was not connected to the patent department. Janssen further objects to this Category in that it is irrelevant as to what searches were performed for any compound other than risperidone. In addition, Janssen objects to this Category because Mylan already had a full opportunity to question Mr. Kennis and Mr. Mertens on this topic and thus any testimony on the topic will likely be duplicative. Subject to these objections, Janssen will provide you with the name of a witness shortly.

3. Any studies or other investigations conducted by Ludo E. J. Kennis or Jan Vandenberg on behalf of Janssen from about 1974 through and including about 1985 regarding prior art or potential prior art to the Identified Piperidinyl Compounds.

Janssen objects to this Category due to applicable protected (privileged) communications. Janssen objects to this Category due to Mylan's inaccurate definition of "prior art." As was clearly stated at the Kennis and Merten depositions, the "prior art department" at Janssen had nothing to do with searching for prior art as it pertains to 35 U.S.C. §§ 102 and/or 103. Rather, the department performed literature searches to help perform the synthesis of various compounds. Thus, the prior art department was not connected to the patent department. Janssen further objects to this Category in that it is irrelevant as to what searches were performed for any compound other than risperidone. Janssen further objects to this Category because Mylan already had an opportunity to question Mr. Kennis himself relating to this Category and, ~~as you are aware, Mr. Vandenberg has passed away. Thus, Janssen will not produce a witness for this Category.~~

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4. Corroboration, including but not limited to any communication or other transmission of information, between Janssen's Prior Art Studies (department) and its Patent Department from about 1975 through and including about 1985 regarding identified prior art or potential prior art to the Identified Piperidinyl Compounds.

Janssen objects to this Category due to applicable protected (privileged) communications. Janssen objects to this Category because it is unclear what is meant by the use of the term "corroboration." Because this Category is too vague and ambiguous for Janssen to understand what it means, Janssen will not produce a witness for this Category.

5. Corroboration, including but not limited to any communication or other transmission of information, between or among Ludo E. J. Kennis or Jan Vandenberg, and either or both of Janssen's Prior Art Studies (department) and its Patent Department, from about 1975 through and including about 1985 regarding identified prior art or potential prior art to the Identified Piperidinyl Compounds.

Janssen objects to this Category due to applicable protected (privileged) communications. Janssen objects to this Category because it is unclear what is meant by the use of the term "corroboration." Because this Category is too vague and ambiguous for Janssen to understand what it means, Janssen will not produce a witness for this Category.

Notice #2

1. Pharmacological, animal, pre-clinical, clinical, receptor-binding and other testing of ketanserin from the date of its first synthesis by Janssen through and until approximately April of 1985.

Janssen objects to this Category as being overbroad in that it requests testimony regarding "pharmacological, animal, pre-clinical, clinical, receptor-binding and other testing." Mylan has not defined what is meant by "receptor-binding," "clinical," "pre-clinical," and "animal" testing. Janssen also objects because this Category requires one witness to testify on many different testing procedures encompassing many different areas of expertise. Although Janssen will try to prepare someone to testify about the general pharmacological testing of this compound, it will not be possible for any one witness to testify on all these different testing methodologies and results. We suggest that in advance of the deposition you provide us with the specific testing you are interested in so that we can attempt to prepare the witness accordingly. Subject to these objections, Janssen will provide you with the name of a witness to testify on this Category shortly.

2. Pharmacological, animal, pre-clinical, clinical, receptor-binding and other testing of pirenperone from the date of its first synthesis by Janssen through and until approximately April of 1985.

~~Janssen objects to this Category as being overbroad in that it requests testimony regarding "pharmacological, animal, pre-clinical, clinical, receptor-binding and other testing."~~

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November 5, 2004
Page 4

Mylan has not defined what is meant by "receptor-binding," "clinical," "pre-clinical," and "animal" testing. Janssen also objects because this Category requires one witness to testify on many different testing procedures encompassing many different areas of expertise. Although Janssen will try to prepare someone to testify about the general pharmacological testing of this compound, it will not be possible for any one witness to testify on all these different testing methodologies and results. We suggest that in advance of the deposition you provide us with the specific testing you are interested in so that we can attempt to prepare the witness accordingly. Subject to these objections, Janssen will provide you with the name of a witness to testify on this Category shortly.

3. Pharmacological, animal, pre-clinical, clinical, receptor-binding and other testing of compound 10 and compound 11 from the date of its first synthesis by Janssen through and until approximately January of 1994.

Janssen objects to this Category as being overbroad in that it requests testimony regarding "pharmacological, animal, pre-clinical, clinical, receptor-binding and other testing." Mylan has not defined what is meant by "receptor-binding," "clinical," "pre-clinical," and "animal" testing. Janssen also objects because this Category requires one witness to testify on many different testing procedures encompassing many different areas of expertise. Although Janssen will try to prepare someone to testify about the general pharmacological testing of this compound, it will not be possible for any one witness to testify on all these different testing methodologies and results. We suggest that in advance of the deposition you provide us with the specific testing you are interested in so that we can attempt to prepare the witness accordingly. Subject to these objections, Janssen will provide you with the name of a witness to testify on this Category shortly.

4. Pharmacological, animal, pre-clinical, clinical, receptor-binding and other testing of risperidone from the date of its first synthesis by Janssen through and until approximately April of 1985.

Janssen objects to this Category as being overbroad in that it requests testimony regarding "pharmacological, animal, pre-clinical, clinical, receptor-binding and other testing." Mylan has not defined what is meant by "receptor-binding," "clinical," "pre-clinical," and "animal" testing. Janssen also objects because this Category requires one witness to testify on many different testing procedures encompassing many different areas of expertise. Although Janssen will try to prepare someone to testify about the general pharmacological testing of this compound, it will not be possible for any one witness to testify on all these different testing methodologies and results. We suggest that in advance of the deposition you provide us with the specific testing you are interested in so that we can attempt to prepare the witness accordingly. Subject to these objections, Janssen will provide you with the name of a witness to testify on this Category shortly.

5. The pharmacological, animal, pre-clinical, clinical, receptor-binding and other testing of any salts, hydrates, polymorphs, active moieties and physical states thereof (including

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Page 5

intermediates), as well as all dosage forms such as oral or injectable formulations, of ketanserin, pirenperone, compound 10, compound 11 and risperidone from the date Janssen first synthesized each such compound through and until approximately January of 1994.

Janssen objects to this Category as being overbroad in that it requests testimony regarding "pharmacological, animal, pre-clinical, clinical, receptor-binding and other testing." Mylan has not defined what is meant by "receptor-binding," "clinical," "pre-clinical," and "animal" testing. Janssen also objects because this Category requires one witness to testify on many different testing procedures encompassing many different areas of expertise. Although Janssen will try to prepare someone to testify about the general pharmacological testing of these compounds, it will not be possible for any one witness to testify on all these different testing methodologies and results. We suggest that in advance of the deposition you provide us with the specific testing on specific molecules you are interested in so that we can attempt to prepare the witness accordingly. Janssen further objects to this Category in that it requests testimony related to "all dosage forms such as oral or injectable formulations." The different oral dosage formulations tested by Janssen are not at issue in this case and Janssen will not provide a witness to testify on this topic. Subject to these objections, Janssen will provide you with the name of a witness to testify on portions of this Category shortly.

6. Janssen's filing with the United States Food & Drug Administration of any New Drug Application, Abbreviated New Drug Application, Drug Master File or Investigational New Drug Application with respect to the Identified PiperidinyI Compounds.

Janssen objects to this Category in that it is seeking testimony that is irrelevant to the issues in this case. The FDA filings related to any of these compounds is irrelevant to this case. Thus, Janssen will not produce a witness on this Category.

Notice #3

1. The facts and circumstances that form the basis of Janssen's assertion, if any, that ketanserin, pirenperone, risperidone, compound 10, compound 11, or any compound claimed or disclosed in the '663 patent has enjoyed commercial success, including but not limited to, advertising expenditures and sales growth.

Janssen objects to this Category because it requests testimony relating to a legal conclusion and thus is more suitable in the form of a contention interrogatory rather than a 30(b)(6) topic. Janssen will not provide a contention 30(b)(6) witness when a contention interrogatory is more appropriate. *See McCormick-Morgan, Inc. v. Teledyne Industries, Inc.*, 134 F.R.D. 275 (N.D. Cal. 1991); *Exxon Research & Eng'g v. U.S.*, 44 Fed.Cl. 597 (Fed.Cl. 1999). However, Janssen will provide a witness to testify generally about the sales and marketing of risperidone and compounds 10 and 11. Janssen objects to providing any testimony relating to the sales and marketing of ketanserin and pirenperone since they are not compounds claimed in the '663 patent. Subject to these objections, Janssen will provide you with the name of a witness to testify on portions of this Category shortly.

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Page 6

2. The facts and circumstances that form the basis of Janssen's assertion, if any, that the commercial success of risperidone has a nexus to any claim or claims of the '663 patent.

Janssen objects to this Category because it requests testimony relating to a legal conclusion and thus is more suitable in the form of a contention interrogatory rather than a 30(b)(6) topic. Janssen will not provide a contention 30(b)(6) witness when a contention interrogatory is more appropriate. *See McCormick-Morgan, Inc. v. Teledyne Industries, Inc.*, 134 F.R.D. 275 (N.D. Cal. 1991); *Exxon Research & Eng'g v. U.S.*, 44 Fed.Cl. 597 (Fed.Cl. 1999). However, Janssen will provide a witness to testify generally about the sales and marketing of risperidone. Subject to these objections, Janssen will provide you with the name of a witness to testify on portions of this Category shortly.

3. The facts and circumstances that form the basis of Janssen's assertion, if any, that there are surprising or unexpected results for ketanserin, pirenepone, risperidone, compound 10, compound 11, or any compound claimed or disclosed in the '663 patent with respect to any of the aforementioned compounds or any prior art.

Janssen objects to this Category because it requests testimony relating to a legal conclusion and thus is more suitable in the form of a contention interrogatory rather than a 30(b)(6) topic. Janssen will not provide a contention 30(b)(6) witness when a contention interrogatory is more appropriate. *See McCormick-Morgan, Inc. v. Teledyne Industries, Inc.*, 134 F.R.D. 275 (N.D. Cal. 1991); *Exxon Research & Eng'g v. U.S.*, 44 Fed.Cl. 597 (Fed.Cl. 1999). Thus, Janssen will not provide a witness to testify on this Category.

4. The facts and circumstances that form the basis of Janssen's assertion, if any, that a long-felt need was filled by ketanserin, pirenepone, risperidone, compound 10, compound 11, or any compound claimed or disclosed in the '663 patent.

Janssen objects to this Category because it requests testimony relating to a legal conclusion and thus is more suitable in the form of a contention interrogatory rather than a 30(b)(6) topic. Janssen will not provide a contention 30(b)(6) witness when a contention interrogatory is more appropriate. *See McCormick-Morgan, Inc. v. Teledyne Industries, Inc.*, 134 F.R.D. 275 (N.D. Cal. 1991); *Exxon Research & Eng'g v. U.S.*, 44 Fed.Cl. 597 (Fed.Cl. 1999). Thus, Janssen will not provide a witness to testify on this Category.

5. Why Janssen chose and continued to develop, as a commercial product for humans, risperidone from among the compounds claimed or disclosed in the '663 patent.

Janssen objects to this Category in that it is duplicative of Category 1 of Mylan's Notice of 30(b)(6) Deposition dated October 5th, 2004. Mylan has already had a full and fair opportunity to question Mr. Kennis as a 30(b)(6) witness on this Category and Janssen will not have Mr. Kennis testify on this Category again.

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Page 7

6. Why Janssen discontinued the development as a commercial product for humans, with the exception of risperidone, the compounds claimed or disclosed in the '663 patent.

Janssen objects to this Category in that it is duplicative of Category 1 of Mylan's Notice of 30(b)(6) Deposition dated October 5th, 2004. Mylan has already had a full and fair opportunity to question Mr. Kennis as a 30(b)(6) witness on this Category and Janssen will not have Mr. Kennis testify on this Category again.

7. Other's praise, skepticism, failures, teaching away, or copying relating to ketanserin, pirenperone, risperidone, compound 10, compound 11, or any compound claimed or disclosed in the '663 patent.

Janssen objects to this Category because it requests testimony relating to a legal conclusion in its use of the term "teaching away" and thus is more suitable in the form of a contention interrogatory rather than a 30(b)(6) topic. Janssen will not provide a contention 30(b)(6) witness related to "teaching away" when a contention interrogatory is more appropriate. *See McCormick-Morgan, Inc. v. Teledyne Industries, Inc.*, 134 F.R.D. 275 (N.D. Cal. 1991); *Exxon Research & Eng'g v. U.S.*, 44 Fed.Cl. 597 (Fed.Cl. 1999). Janssen will provide a witness to generally testify to other's praise, skepticism, failures, and copying relating to risperidone, compound 10, and compound compound 11. Janssen objects to providing any testimony relating to other's praise, skepticism, failures, and copying relating to ketanserin and pirenperone since they are not compounds claimed in the '663 patent. Subject to these objections, Janssen will provide you with the name of a witness to testify on portions of this Category shortly.

Very truly yours,



Scott M. Brown

cc: Alan Pollack